

REMARKS

Applicants have concurrently filed a Request for Continued Examination and, therefore, respectfully request consideration of the above amendments and the following remarks prior to further examination of the present application.

Claims 91, 93-104, 106, 108-112, 114, 116 and 117 are currently pending in this application. Claims 91, 101, 104, 106, 108, 110, 111, 112, 114, 116 and 117 have been amended. Claims 54, 55, 62-78, 80, 81, 83-90 and 119 have been cancelled. Claims 54, 55, 62-78, 80, 81 and 83-90 have been cancelled as the result of a restriction requirement. Applicants retain the right to present claims 54, 55, 62-78, 80, 81 and 83-90 in a divisional application.

Applicants' Response to Double Patenting Rejection

Claim 119 is rejected under the doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 1 of co-pending Application No. 10/768,809 in view of U.S. Patent No. 5,044,761 to Yuhki et al. (hereinafter "Yuhki"). Claim 119 has been cancelled, and thus, the double patenting rejection has been obviated. Withdrawal of this rejection is respectfully requested.

Applicants' Response to 35 U.S.C. §112, Second Paragraph Rejection

Claims 91-104, 106, 108-112, 114, 116, 117 and 119 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Applicants amended claims 91, 101, 104, 106, 108, 110, 111, 112, 114, 116 and 117 in its response after final dated May 9, 2006 to address these Section 112 rejections. As these amendments were entered after final for purposes of appeal, Applicants respectfully submit that the Section 112 rejections have been overcome. Withdrawal of this rejection is respectfully requested.

Applicants' Response to Rejection under 35 U.S.C. §103 over Zerbe in view of Strobush and Yuhki

Claims 91, 93, 97, 100, 101, 106, 108, 109, 111, 112, 114, 117 and 119 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 6,660,292 to Zerbe et al. (hereinafter "Zerbe") in view of U.S. Patent No. 5,881,476 to Strobush et al. (hereinafter "Strobush") and Yuhki. Applicants respectfully submit that the cited combination fails to render the claims obvious, as amended herein.

Applicants have amended all of the currently pending independent claims to further define the invention. In particular, Applicants have amended independent claims 91, 101, 104, 106, 108, 110, 111, 112, 114, 116 and 117 to specify a number of the process parameters involved in the present invention.

First, the amended claims all require the active component to be "drug particles".

Second, the amended claims all require formation of the wet film to occur by "coating or casting the film".

Third, the drying conditions have been further clarified. Drying times and temperatures have been specified. The amended claims also clarify that drying occurs in two stages. As required by the amended claims, the overall drying process occurs "within about 10 minutes or fewer". As part of this overall drying, a visco-elastic film is initially formed "within about the first 4.0 minutes". Then the film is further dried to achieve the final dried film product. In addition, the amended claims require that the hot air currents are applied "at temperatures of about 60°C to about 100°C".

Fourth, the claims have been amended to specify that the visco-elastic film formed in the initial drying stage includes the “drug particles uniformly distributed throughout”. Further, the controlled drying parameters prevent aggregation or conglomeration “of said drug particles”. Also, the final dried film product includes the “drug particles uniformly distributed throughout”.

These amendments are supported by disclosure appearing on pages 12, 13, 17, 26, 28, 37 (Table 7) and Fig. 6 of the application.

The cited combination of Zerbe, Strobush and Yuhki fails to disclose or suggest Applicants’ claims, as amended herein to include these specific process parameters. Nowhere in Zerbe, Strobush or Yuhki is it disclosed or suggested to dry an edible thin film for delivery of a drug in the two-stage manner recited in the amended claims. In particular, the amended claims require that the films undergo overall drying within about 10 minutes or fewer. As part of that overall drying process, a visco-elastic film having drug particles uniformly distributed throughout is initially created within about the first 4.0 minutes. The visco-elastic film is formed by applying hot air currents to the bottom side of the surface with substantially no top air flow. The hot air currents are applied at temperatures of about 60-100°C. This locks in the uniformity of components, including the drug particles, distributed uniformly throughout the film matrix. Then, the film is further dried. As specified by the overall drying time, such further drying proceeds up to about 10 minutes. Therefore, the films are dried in a two-stage manner with initial drying requirements that lock in the uniformity of the components within the film, and then further drying to achieve the final self-supporting film product.

Such specific drying parameters are not disclosed or suggested in Zerbe, Strobush or Yuhki. None of these references disclose or suggest a two-stage drying process in which compositional uniformity is achieved in the first part and then maintained upon further drying until the final dried film product is obtained. Nor are the specific drying times and temperatures for this two-stage process disclosed or suggested. Moreover, there would be no reason for one skilled in the art to modify the teachings of the cited art in attempt to achieve Applicants’

claimed process. There is simply no appreciation of the need for, or the problems faced in, achieving compositional uniformity in a film delivery system for drugs. In Zerbe, conventional air drying in an oven is used. Though Strobush discloses a more complex drying apparatus, there would be no reason for one skilled in the art to alter this apparatus in an attempt to achieve Applicants' two-stage drying process with its specific parameters. Yuhki adds nothing to the drying disclosure of these references.

Uniformity of content in the final film, and creating a film with a uniform distribution of drug particles, were not problems identified or recognized by the prior art. Thus, there was no impetus or reason to modify the prior art processes in a manner directed at addressing these problems. Yet, even if one of ordinary skill in the art was prompted to look for an adaptation of the known processes of drying film, independent of solving these specific problems, there is nothing which directs the skilled artisan to combine the process steps and parameters as claimed to achieve and maintain uniformity of drug particles and ultimate uniformity of content of the composition. The USPTO's own guidelines provided to the Examiners make it clear that if there is a lack of incentive to make a change, or if the change to be made is not one which varies the prior methods in a predictable way to result in the claimed invention, then "this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art." *See* MPEP §2143 (Rationale F).

As such, and in view of the rationales set forth in the MPEP for determining obviousness under *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. ___, 82 U.S.P.Q. 1385 (2007), it would not have been predictable to one skilled in the art to vary the teachings of these references to include all of Applicants' specifically recited drying parameters in attempt to achieve a self-supporting film containing drug particles uniformly distributed throughout. *See* MPEP §§ 2141, 2143 (Rationale F).

In view thereof, Applicants respectfully submit that the cited combination of Zerbe, Strobush and Yuhki fails to disclose or suggest amended claims 91, 101, 104, 106, 108, 110,

111, 112, 114, 116 and 117. As such, claims 91, 101, 104, 106, 108, 110, 111, 112, 114, 116 and 117, and all claims that depend therefrom, are patentable over Zerbe, Strobush and Yuhki, each taken alone or in combination.

It also should be noted that, in addition to the amendments discussed above, Applicants have further amended claim 117. These amendments further define the specific apparatus and types of actives used in the process of this embodiment. In particular, this embodiment of the present invention is described on page 16 and shown in Fig. 6 of the application. As discussed therein, this embodiment involves multiple mixing stages and is particularly useful for actives that degrade with prolonged exposure to water, air or another polar solvent. (Page 13, ¶ [0043]). The formation of a premix of polymer and water and subsequent addition of the active in a separate mixer down the line preserves its activity.

Accordingly, claim 117 has been amended to specify that this process is used for drugs that “degrade with prolonged exposure to water”. Claim 117 additionally has been amended to recite the features of the apparatus shown in Fig. 6, which are useful in preserving the activity of such sensitive drugs. As recited in the claim, the masterbatch premix is formed in step (a). As recited in amended step (c), a predetermined amount of the premix is fed to at least one of a first mixer and a second mixer, shown as 30, 30’ in Fig. 6, via a first metering pump 26 and a control valve 28. The drug particles then are added to at least one of these first and second mixers in amended step (d). After mixing in the drug particles to form a uniform matrix, a specified amount of this matrix is fed to a pan in newly added step (f), shown as 36 in Fig. 6, through at least one second metering pump, shown as 34, 34’. A wet film then is formed from the matrix in amended step (g) “within a time period before the active degrades by coating or casting the film with one or more rollers”. These rollers are shown as 38 and 40 in Fig. 6.

None of these amended or newly recited steps are disclosed or suggested in Zerbe, Strobush or Yuhki. Nor is there any appreciation in the cited references for the importance of adding drugs that may degrade upon prolonged exposure to water at a later stage in the process.

As such, Applicants respectfully submit that claim 117 is additionally patentable over the cited combination of art on this basis.

Applicants' Response to Rejection under 35 U.S.C. §103 over Zerbe in view of Strobush, Yuhki and Horstmann

Claims 94 and 95 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Zerbe in view of Strobush, Yuhki and U.S. Patent No. 5,629,003 to Horstmann et al. (hereinafter "Horstmann"). Applicants respectfully submit that the cited combination fails to render the claims obvious, as amended herein.

Claims 94 and 95 depend from claim 91, and thus, require all of the limitations of claim 91. As discussed in detail above with regard to claim 91, the cited combination of Strobush, Zerbe and Yuhki fails to disclose or suggest all of the process parameters specifically recited in amended claim 91. Horstmann was cited merely for its disclosure relating to film thickness and contains no disclosure of relevance to Applicants' amended process features. Horstmann, therefore, fails to cure the deficiencies of Zerbe, Strobush and Yuhki. As such, it is respectfully submitted that claims 94 and 95 are patentable over Zerbe, Strobush, Yuhki and Horstmann, each taken alone or in combination.

Applicants' Response to Rejection under 35 U.S.C. §103 over Zerbe in view of Strobush, Yuhki and Wittwer

Claim 96 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Zerbe in view of Strobush, Yuhki and U.S. Patent No. 4,478,658 to Wittwer (hereinafter "Wittwer"). Applicants respectfully submit that the cited combination fails to render the claim obvious, as amended herein.

Claim 96 depends from claim 91, and thus, requires all of the limitations of claim 91. As above, the cited combination of Strobush, Zerbe and Yuhki fails to disclose or suggest all of the process parameters specifically recited in amended claim 91. Wittwer was cited merely for its

disclosure relating to film viscosity. Wittwer contains no disclosure of relevance to Applicants' amended process features, and thus, fails to cure the deficiencies of Zerbe, Strobush and Yuhki in this regard. Therefore, it is respectfully submitted that claim 96 is patentable over Zerbe, Strobush, Yuhki and Wittwer, each taken alone or in combination.

Applicants' Response to Rejection under 35 U.S.C. §103 over Zerbe in view of Strobush, Yuhki and Zerbe '957

Claims 98, 99, 102 and 103 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Zerbe in view of Strobush, Yuhki and U.S. Patent No. 6,231,957 to Zerbe et al. (hereinafter "Zerbe '957"). Applicants respectfully submit that the cited combination fails to render the claims obvious, as amended herein.

Claims 98 and 99 depend from claim 91, and thus, require all of the limitations of claim 91. Claims 102 and 103 depend from claim 101, and thus, require all of the limitations of claim 101. Again, as discussed in detail above, the cited combination of Strobush, Zerbe and Yuhki fails to disclose or suggest all of the process parameters specifically recited in amended claim 91, and similarly, amended claim 101. Zerbe '957 was cited merely for its disclosure relating to cutting film into pieces and packaging the films into containers. Zerbe '957 contains no disclosure of relevance to the specifically recited process parameters of Applicants' amended claims. Zerbe '957, therefore, fails to cure the deficiencies of Zerbe, Strobush and Yuhki in this regard. In view thereof, it is respectfully submitted that claims 98, 99, 102 and 103 are patentable over Zerbe, Strobush, Yuhki and Zerbe '957, each taken alone or in combination.

Applicants' Response to Rejections under 35 U.S.C. §103 over Zerbe in view of Strobush, Yuhki and Horstmann

Claims 104 and 110 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Zerbe in view of Strobush, Yuhki and Horstmann. Applicants respectfully submit that the cited combination fails to render the claims obvious, as amended herein.

As discussed in detail above, independent claims 104 and 110 have been amended to recite a number of additional features of the claimed invention. Strobush, Zerbe and Yuhki fail to disclose or suggest all of these specifically recited process parameters, and thus, amended claims 104 and 110 are patentable over this cited combination.

Furthermore, Horstmann was cited merely for its disclosure relating to film thickness and contains no disclosure of relevance to Applicants' amended process features. Horstmann, therefore, fails to cure the deficiencies of Zerbe, Strobush and Yuhki in this regard. In view thereof, it is respectfully submitted that claims 104 and 110 are patentable over Zerbe, Strobush, Yuhki and Horstmann, each taken alone or in combination.

Applicants' Response to Rejection under 35 U.S.C. §103 over Zerbe in view of Strobush, Yuhki and Mehra

Claim 116 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Zerbe in view of Strobush, Yuhki and U.S. Patent No. 5,733,575 to Mehra et al. (hereinafter "Mehra"). Applicants respectfully submit that the cited combination fails to render the claims obvious, as amended herein.

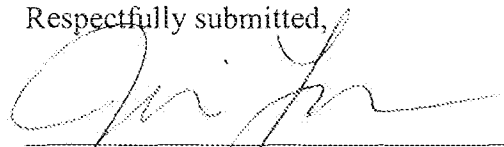
As discussed in detail above, independent claim 116 has been amended to recite a number of additional features of the claimed invention. Strobush, Zerbe and Yuhki fail to disclose or suggest all of these specifically recited process parameters, and thus, amended claim 116 is patentable over this cited combination.

Mehra was cited merely for its disclosure of anti-foaming agents and fails to include any disclosure of relevance to Applicants' amended process recitations. Mehra, therefore, fails to cure the deficiencies of Zerbe, Strobush and Yuhki in this regard. Therefore, it is respectfully submitted that claim 116 is patentable over Zerbe, Strobush, Yuhki and Mehra, each taken alone or in combination.

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In view thereof, claims 91, 93-104, 106, 108-112, 114, 116 and 117 are believed to be in proper form for allowance. A favorable reconsideration of the application on the merits is earnestly solicited. Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

Respectfully submitted,



Jamie M. Larmann
Registration No.: 48,623
Attorney for Applicants

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700